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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,127	09/26/2003	Michael E. O'Donnell	22221/1180 (RU-339)	1311
7590 Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051				
EXAMINER				
HUTSON, RICHARD G				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
11/19/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/673,127

**Applicant(s)**

O'DONNELL ET AL.

**Examiner**

Richard G. Hutson

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants cancellation of claims 1, 2, 5-8 and 11-15, in the paper of 8/20/2008, is acknowledged. Claims 16-19 are at issue and are present for examination. Applicants' arguments filed on 8/20/2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Upon further consideration, it has come to the attention of the examiner that the following rejections are appropriate and thus this action is non-final. Any inconvenience to applicants is regretted.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaboev et al. (J. Bacteriology, Vol 145, No. 1, pp 21-26 1981).

Kaboev et al. teach the purification and properties of DNA polymerase I from *Bacillus stearothermophilus* (See table I and supporting text). Kaboev et al. teach that the DNA polymerase I that they isolated has some differences from that isolated by others and this leads Kaboev et al. to hypothesize that their DNA polymerase I

preparation is not homogeneous and is contaminated with other DNA polymerase activities. Based upon this it is the position of the office that the *Bacillus stearothermophilus* extract taught by Koboiev et al. contains the beta subunit of the DNA polymerase III holoenzyme and the amino acid sequence of SEQ ID NO: 174 of the beta subunit of DNA polymerase III of *Bacillus stearothermophilus* is a feature that is inherent to the subunit. Thus this crude extract taught by Koboiev et al. anticipates claims 16-18 drawn to an isolated beta subunit comprising the amino acid sequence of SEQ ID NO: 174 and a DNA polymerase III holoenzyme comprising this subunit.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janjic et al. (U.S. Patent No. 6,677,146 B1 issued 1/13/2004) and Koboiev et al. (J. Bacteriology, Vol 145, No. 1, pp 21-26 1981).

Janjic et al. teach the gene encoding and amino acid sequences of DNA Polymerase III holoenzyme subunits from a number of thermophilic organisms. In particular Janjic et al. teach the DNA polymerase III holoenzyme subunit and accessory proteins of *T. thermophilus* as well as antibodies, primers, probes and other reagents

useful to identify DNA polymerase III molecules. Janjic et al. specifically teach the cloning and expression of the *dnaN* gene encoding the  $\beta$ -subunit of DNA polymerase III holoenzyme from *E. coli* and *T. thermophilus*, as well as a simple processivity assay for the *T. thermophilus*  $\beta$ -subunit. Janjic et al. also teach the production of polyclonal antibodies against the Tth  $\beta$ -subunit

As discussed above, Kaboev et al. teach the purification and properties of DNA polymerase I from *Bacillus stearothermophilus*. Kaboev et al. teach that the DNA polymerase I that they isolated has some differences from that isolated by others and lead Kaboev et al. to hypothesize that their DNA polymerase I preparation is not homogeneous and is contaminated with other DNA polymerase activities.

One of skill in the art at the time of filing would have been motivated to isolate the beta subunit of the DNA polymerase III holoenzyme of *Bacillus stearothermophilus* using the polyclonal antibodies of Janjic et al. and the *Bacillus stearothermophilus* cell extract of Kobev et al. The motivation to isolate this subunit is to identify those DNA polymerase activities found in the preparation of Kobev et al. The expectation of success is high based upon the high degree of skill in the art with respect to protein purification and the results of both Janjic et al. who successfully isolate the beta subunit of DNA polymerase III from *T. thermophilus* and the results of Kaboev et al. who suggest that polymerase activities in addition to DNA polymerase I exist in their DNA polymerase preparations.

It is noted that the amino acid sequence of SEQ ID NO: 174 of the beta subunit of DNA polymerase III of *Bacillus stearothermophilus* is a feature that is inherent to the subunit. It would have been obvious to put the isolated beta subunit in some sort of container that would have also inherently had some residual dNTPs, Thus meeting the limitation of claim 19. Thus claims 16-19 are obvious over Janjic et al. (U.S. Patent No. 6,677,146 B1 issued 1/13/2004) and Kaboev et al. (J. Bacteriology, Vol 145, No. 1, pp 21-26 1981).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgH

11/14/2008

/Richard G Hutson/  
Primary Examiner, Art Unit 1652